REMARKS

I. Consideration of the Supplemental Information Disclosure Statement

A Supplemental Information Disclosure Statement accompanies this response. Consideration and entry into the record is respectfully requested.

II. Discussion of the Rejection under 35 U.S.C. Sec. 102(e) over Depui *et al.*

Claims 20, 21, 23-26 and 28-32 have been rejected under 35 U.S.C. Sec. 102(e) as allegedly being anticipated by Depui *et al.* (U.S. Patent No. 6,365,184). Applicants respectfully traverse the rejection.

In the Examiner's comments, she admits that the cited reference does not teach the specific weight percent of hydroxypropoxyl groups in the low-substituted hydroxypropyl cellulose that are recited in independent claims 20, 21, 30 and 32. However, she assumes that "the L-HPC of Depui would have a similar percent substitution of the hydroxypropoxyl group because Depui teaches the use of L-HPC to obtain a similar fast disintegrating tabled dosage having disintegration times falling within the claimed range".

Yet, the cited reference does not indicate that bucal dissolution times were tested. Disintegration times were measured in Examples 2 and 5 in Depui *et al.* (examples which include L-HPC as a component). The exact test procedures are not indicated, but there is no suggestion that the disintegration times which the Examiner has focused on were recorded in humans. All that is known is that the disintegration time tests of the '184 reference were performed in water.

It is well-established that disintegration time for a solid will depend upon what fluid and how much of that fluid is utilized for disintegration. We know that water was used in the cited art. But how much water? It is unknown. The more water, the faster a solid may be dissolved. Yet in the mouth, only small amounts of water are available as saliva at any given time. A quick disintegration time in a large volume of water does not suggest that comparably rapid dissolution can occur in the mouth. By the same token, a quick disintegration time in an unknown volume of water does not mean that comparably rapid dissolution time can occur in the mouth.

So the disintegration times recorded in the cited art (presumably not tests with human volunteers) cannot be used to reach a firm conclusion that the cited art's multiple unit tableted dosage form will dissolve bucally in from about 5 to about 50 seconds. And the L-HPC is not specifically described in the reference.

Put another way, the Examiner has assumed a feature of the cited art which is not disclosed (the specific L-HPC recited in independent claims 20, 21, 30 and 32) in the reference. Despite this, she believes that the feature *should* be in the art because she makes a second assumption, that the disintegration times of the art correlate to Applicants' bucal dissolution times. Applicants argue that one assumption cannot be used as the basis for another assumption to reach a conclusion that the reference is anticipatory.

For this reason, Applicants do not believe that the cited art anticipates the aspects of their invention as set forth in independent claims 20, 21, 30 and 32, as the cited art does not disclose a low-substituted hydroxypropylcellulose having 5 to 7% by weight of hydroxypropoxyl groups. Furthermore, the rapid disintegration time of the cited art is different from Applicants' bucal dissolution times.

Claims 23-26 depend upon claim 20; claims 28 and 29 depend upon claim 21 and claim 31 depends upon claim 30. Applicants submit that the more specific dependent claims are also not anticipated by the cited reference for the reason provided above.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 102(e) rejection.

III. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Depui *et al.* in view of Makino *et al.*

Claims 20, 21, 23-26 and 28-32 have been rejected under 35 U.S.C. Sec. 103(a) as allegedly unpatentable over Depui *et al.* (U.S. Patent No. 6,365,184) in view of Makino *et al.* (U.S. Patent No. 5,026,560). Applicants respectfully traverse the rejection.

Applicants hereby incorporate their arguments with respect to Depui *et al.* from Sec. II above, which they believe prove that the cited art neither teaches nor suggests the present invention as set forth in the pending claims.

The deficiencies of Depui *et al.* are not cured by Makino *et al.* In Experimental Example 1, disintegration time of a minute was obtained for granules. The Examiner has assumed that this disintegration time is comparable enough to that which would be obtained orally.

As stated above, such assumption cannot be made.

Another difference is that the examples of Makino *et al.* only include L-HPC having 10-13 % substitution with hydroxypropoxyl groups. There are no examples of the presently claimed L-HPC. Here again, the Examiner uses an assumption as the basis for a further assumption, which is itself without basis in stating that "it would have been obvious for one of ordinary skill in the art to, by routine experimentation select L-HPC having a content of the hydroxypropoxyl group from about 4 as disclosed in col. 1 lines 64-67 with the expectation of providing a faster dosage form".

The disintegration time indicated in each of the cited references cannot be correlated directly to the claimed bucal dissolution times in independent claims 20 and 21. So the combined teachings of the cited references do not render the present invention as set forth in the pending claims obvious.

In addition, there is no teaching or suggestion in either cited reference, nor the combination thereof, of tablets having improved in chalky taste and no roughness as set forth in independent claims 30 and 32.

Claims 23-26 depend upon claim 20; claims 28 and 29 depend upon claim 21 and claim 31 depends upon claim 30. Applicants submit that the more specific dependent claims are also not rendered obvious by the combined teachings of the cited references for the reason provided above.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) rejection over Depui *et al* in view of Makino *et al.*

IV. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Depui *et al.* in view of Ohno *et al.*

Claims 20, 21, 23-26 and 28-32 have been rejected under 35 U.S.C. Sec. 103(a) as allegedly unpatentable over Depui *et al.* (U.S. Patent No. 6,365,184) in view of Ohno *et al.* (U.S. Patent No. 5,958,453). Applicants respectfully traverse the rejection.

Applicants hereby incorporate their arguments with respect to Depui *et al.* from Sec. II above, which they believe prove that the cited art neither teaches nor suggests the present invention as set forth in the pending claims.

The deficiencies of Depui *et al.* are not cured by Ohno *et al.* The Ohno *et al.* reference has already been discussed extensively during the lengthy prosecution of the present application. To summarize some of the previous arguments, the Examiner is requested to review again the information that in the comparative examples 3, 4 and 5 of the '453 reference, wherein an L-HPC was included in formulations, bucal dissolution time was considerably longer than the 0.1-1.0 minute range cited in col. 6, lines 66 and 67. Thus the Examiner is incorrect in stating that Ohno *et al.* teach the use of L-HPC to obtain dosage forms that exhibit a disintegration time of less than 60 seconds.

Therefore, neither cited reference teaches the bucal dissolution times recited in independent claims 20 and 21. So the combined teachings of the cited references do not render the present invention as set forth in the pending claims obvious.

In addition, there is no teaching or suggestion in either cited reference, nor the combination thereof, of tablets having improved in chalky taste and no roughness as set forth in independent claims 30 and 32.

Claims 23-26 depend upon claim 20; claims 28 and 29 depend upon claim 21 and claim 31 depends upon claim 30. Applicants submit that the more specific dependent claims are also not rendered obvious by the combined teachings of the cited references for the reason provided above.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) rejection over Depui *et al* in view of Ohno *et al.*

V. Discussion of the Additionally Cited Art

Applicants wish to thank the Examiner for bringing the additionally cited art of Yabuki *et al* and Yamaguchi *et al.* to their attention. Applicants have carefully reviewed the references and do not believe that they detract from the patentability of the subject invention.

VI. Conclusion

Reconsideration of the claims and allowance is requested.

Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

Dated: October 14, 2004

Elaine M Ramesh

(847) 383-3391
(847) 383-3372

Elaine M. Ramesh, Ph.D., Reg. No. 43,032
Mark Chao, Ph.D., Reg. No. 37,293
Attorney for Applicants
Customer No. 23115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA

Certificate of Mailing under 37 CFR 1.10

The undersigned hereby certifies that this document, along with any attachments, is being deposited in an envelope addressed to The Commissioner of Patents and Trademarks, with sufficient postage with the United States Postal Service EXPRESS MAIL Post Office to Addressee Service on this date October 14, 2004

Express Mail Label No. EV 524906067 US

Gail L. Winokur

Printed Name: Gail L. Winokur